

# Policy Analysis Of Iranian Pharmaceutical Sector; A Qualitative Study

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**Introduction:** Improving public health through providing affordable and accessible pharmaceuticals is among the concerns of governments worldwide. This study aimed to analyze Iran's pharmaceutical sector policies in order to identify the challenges and suggest some strategic solutions to overcome such challenges.

**Methods:** Top managers (15), middle managers (10), and operational managers (5) working in the Food and Drug Administration of Iranian Ministry of Health along with community pharmacists (5) participated in a qualitative study using semi-structured in-depth interviews. Data were recorded, transcribed, and then analyzed via MAXQDA 10 software.

**Results:** Policies for national pharmaceutical sector were divided into four groups of "research & development", "import & export", "pharmaceutical procurement", and "pharmaceutical supply and distribution". Then, the challenges faced by each sector were extracted. Considering the challenges, some policy options were recommended for growth and development of national pharmaceutical sector.

**Conclusion:** Iran's pharmaceutical sector has managerial and administrative differences compared with overseas pharmaceutical sectors. These differences are the main reasons for the current status of Iran's pharmaceutical sector and have put Iran behind foreign pharmaceutical sectors. Iran's pharmaceutical sector has endured many critical periods during recent decades and has gained great experience during these stages. Therefore, it is believed that Iran's pharmaceutical sector, with its experience and potential, is capable of producing world-level medicines.

**Keywords:** pharmaceutical policy-making, research & development, qualitative study, supportive policy, Iran

## Introduction

Pharmaceutical sector policies – as a sub-branch of health sector policies – may affect the public's access to safe and effective medications and provide some policy options for health policy-makers.<sup>1</sup> High demand for expensive and high tech medications by both patients and doctors has increased the health sector's expenditure during recent years.<sup>2</sup> Analyses carried out on Iran's pharmaceutical market have revealed some dramatic growth within this sector.<sup>3,4</sup> Data suggest that medication costs have raised from \$2.28 in 1997 to \$34.43 in 2010. Iran's pharmaceutical sector suffers from issues such as difficulties in financial exchanges to import some medications, and low value of Rial in comparison to Dollar which are all due to sanctions.<sup>5</sup> In other words, although there have been no direct sanctions on Iran's pharmaceutical sector, since the banks and the system through which the money is being paid for medications is practically closed on Iran, these sanctions affect the

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pharmaceutical sector indirectly.<sup>1,5</sup> On the other hand, having more than 90 pharmaceutical industries widespread around the country has reduced economies to scale as well as their profits.<sup>5</sup> Moreover, the existence of some semi-public pharmaceutical companies has reduced the competition among pharmaceutical companies. From the producers' point of view, pharmaceutical pricing has been the most challenging issue in recent years. Therefore, the reference pricing method has been used to meet this challenge in Iran's pharmaceutical sector.<sup>6,7</sup>

Government's supportive policies for internal production is one of the other issues around the world. Iranian government has also implemented some policies such as creating tariff and non-tariff barriers or even banning importing of some medications in order to support national production.<sup>8</sup> However, these policies have raised some concerns such as limiting patients' choices, the question of whether national production is more cost-effective or not, and even promoting the culture of irrational use of medicines.<sup>5</sup> Moreover, published studies have shown that research and development is the main weakness of Iran's pharmaceutical sector.<sup>6</sup> R&D is costly and a long-term strategy. However, most of the pharmaceutical companies have neither the money nor the time to invest in this area. Iranian government has also taken some measures to motivate pharmaceutical companies to advance their R&D activities.<sup>1,5</sup> If the pharmaceutical industry experiences significant and considerable growth, then, both essential and non-essential drugs will be provided for the public with high quality and proper price. In addition, this will also affect the people and can improve public health, and we will have healthier people at work.<sup>9-11</sup> Since pharmaceutical policies and interventions are the most important and effective policies within the health sector, they must be chosen and implemented based on logical evidence.<sup>1</sup> Countries around the world have been trying to provide high quality and effective medicines for their people. Demographic developments such as ageing, emergence of new medicines, etc., have turned pharmaceutical policy-making into a challenging issue.<sup>12,13</sup> Policy makers should apply the most suitable policy for the pharmaceutical sector so that they can respond to pharmaceutical needs of the public. Such policies should also be revised and modified according to both internal and external factors.

## Iranian Pharmaceutical Sector

Iranian Food and Drug administration, which is a sub-branch of Iranian Ministry of Health (MOH), is responsible for the management and regulation of the Iranian

pharmaceutical sector, including biological and herbal products.<sup>3</sup> The national regulatory system of Iran is composed of two main sectors; pharmaceutical affairs and the national control laboratory.<sup>5</sup> The former is responsible for supervision of manufacturing, distribution, and importation of medicines. The latter checks the quality, origin, etc. of the medicines. Registration is the main and the most important requirement for marketing of medicines in Iran. First, Iran's Drug Selection Committee evaluates the new medicines for inclusion in the Iran Drug list based on their safety, efficacy, and cost-effectiveness. The registration process may take up to one year and even longer. Nonetheless, the process is not always clear and based on the announced guidelines.<sup>14</sup> Iranian Medical Insurance Council evaluates the medicines included in the Iran Drug List and if approved, they would be included in the national health system and reimbursed, up to 90% for inpatients and 70% for outpatients, by the national insurance scheme.<sup>15</sup>

With regard to what has been mentioned previously and considering that medicines play a fundamental role in maintaining and promoting public health, this study aimed to analyze Iran's pharmaceutical sector policies and develop some practical solutions in order to help it grow and progress.

## Methods

### Study Design

In this study, Iran's pharmaceutical sector policies were investigated in order to identify the challenges and suggest some strategic solutions to overcome them. Considering the topic and the necessity for deep understanding and explaining of the pharmaceutical sector policies as well as the ambiguity of pharmaceutical policy-making process, a qualitative design, using semi-structured in-depth interviews, was employed.

An interview guide was developed after performing a comparative study, reviewing the national pharmaceutical documents, and using experiences of professional individuals. The questions of interview guide were reviewed and modified by several members of the research team and then pilot tested with two participants before the start of the main interviews. The final interview guide covered the following items: content of the pharmaceutical policies and regulations; approaches for pharmaceutical policy-making; the effect of the contextual factors on policy-making process; actors and stakeholders involved in

policy-making process; and supportive policies for R&D, procurement, import & export, supply and distribution sectors ([Appendix](#)).

## Data Collection And Analysis

Operational, middle, and top managers working in food and drug administration of Iranian Ministry of Health along with community pharmacists were recruited at pharmacies and Ministry of Health in Tehran, capital city of Iran. Because of the study characteristics and difficulty in access to individuals who agreed to take part in the study, purposive sampling with maximum variations as well as snowball sampling were used. Those pharmacists and managers with at least three years of work experience in their current position were included in the study. 37 pharmacists and healthcare managers were invited to take part in the study; however, two of them declined to participate due to issues related to their position in the Ministry of Health. Finally, 35 of them agreed to take part in the study. All of them gave verbal consent and the ethics committee of Tehran University of medical sciences granted the ethical approval (ethics code: 911119006-1).

The interviews were performed from April to February 2018. 15 participants were top managers, 10 middle managers, and 5 operational managers, and 5 participants were head pharmacists of community pharmacies.

Using the developed interview guide, the semi-structured in-depth face-to-face interviews were conducted in Persian with the participants in their workplaces at a date and time convenient for them by two trained PhD students of Health Policy. Two initial pilot interviews were undertaken in order to improve the interview guide, particularly the interview questions. Recruitment of participants continued until data saturation was reached and no extra information, including new themes/concepts, was revealed.<sup>16</sup>

The interviews were recorded using a digital recorder and transcribed by the two interviewers for analysis and were then analyzed using MAXQDA10 software. Interviews lasted between 30 to 80 mins.

The qualitative content analysis method described by Graneheim and Lundman (2004)<sup>17</sup> was used to inductively analyze the data. Content analysis is a method of analyzing written or verbal data in a systematic way.<sup>18</sup> It focuses on subject and context and highlights variation between the texts; therefore giving the researchers an opportunity to analyze manifest and descriptive content as well as latent and interpretative content.<sup>17</sup>

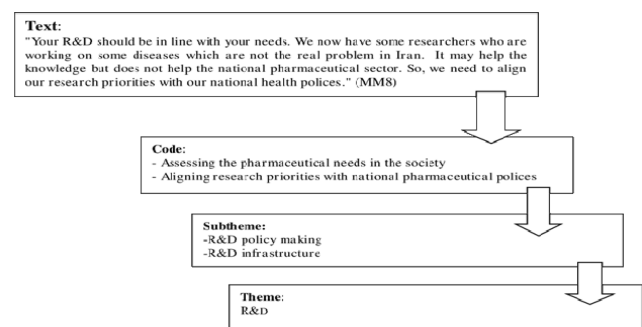
First, the interviews were read several times in order to obtain a sense of the whole. Then, the text was divided into meaningful units that were summarized, coded, and organized into groups with similar content as a form of data categorization. These were then abstracted into sub-themes. The subthemes were subsequently abstracted into emerging themes. Three researchers (HS, AS and FE) discussed and revised the emerging themes. Then, through a process of reflection and discussion, the researchers agreed on how to sort the data. Finally, the underlying meaning, which is the hidden concept, of the categories was assigned a final theme.

In addition, clear analysis guidelines were used in order to limit risks of errors, and to ensure the dependability, transferability, confirmability, and credibility.<sup>19</sup> Long and continued involvement with the data through repeated review and discussion of the interview transcripts by the research team helped us have a deeper understanding of the data and ensured the credibility of the study. Independent review of the transcripts by researchers with diverse clinical and research experience improved the dependability of the theme identification. Contextual data from the setting were reported to enable reviewers/readers to evaluate applications to other settings. [Figure 1](#) shows an example of the data synthesis process from a free text data sample to code, subthemes and final theme.

## Results

A total of 35 participants were recruited for the present study. The mean number of years of work experience of the participants was 6.8. 75% of them were males and the rest were females ([Table 1](#)).

As pointed out by the participants of this study, there are four important sections for a pharmaceutical sector. These sections include R&D, import and export, procurement, and supply and distribution. Considering these sections, we



**Figure 1** An example of the process of development of codes, subthemes, and themes.

**Table 1** Socio-Demographic Characteristics Of The Participants (N=35)

Socio-demographic Characteristics	Number Of Top Managers	Number Of Middle Managers	Number Of Operational Managers	Number Of Community Pharmacists	Total Number
Gender					
Female	2	4	2	1	9
Male	13	6	3	4	26
Age (years)					
<30	2	4	2	0	8
30–50	6	5	3	3	17
>50	7	1	0	2	10
Professional experience (years)					
3–10	4	5	3	2	14
10–15	7	4	1	2	14
>15	4	1	1	1	7

developed a conceptual framework and extracted the themes and sub-themes accordingly (Table 2).

In the following parts, we are going to discuss the extracted themes and sub-themes in detail.

## Theme One: Research And Development

The rate of investment in R&D is one of the main determinants of a successful pharmaceutical sector. The participants stated that there are some challenges for Iranian pharmaceutical sector with regard to their R&D activities. These challenges as well as the solutions provided by interviewees and experts are listed in Table 3.

One of the main issues for the R&D sector is that since these activities are not strategically disciplined, most of them are not in accordance with public needs. One of the informants said,

Your R&D should be in line with your needs. We now have some researchers who are working on some diseases which are not the real problem in Iran. It may help the knowledge but does not help the national pharmaceutical sector. So, we need to align our research priorities with our national health policies. (MM8)

Another participant also pointed out, “Each pharmaceutical company has its own R&D center and they are really active, however what they do is not in line with social needs.” (TM12)

Not having enough investment in R&D activities is one of the other challenges for national pharmaceutical companies. According to one of the informants,

You go and have a look at the financial turnover of international pharmaceutical companies, then you compare their investment in R&D with our national companies. It is disappointing when you find out how deep this difference is. (MM 5)

Research and development is a very long process and requires proper financial investment. This may not be managed by one solo company. Most of the famous companies around the world are multi-national and have shareholders from various countries. Thus, if we can have a joint venture between our national companies, it may bring about some promising results in the long-run. One of the participants mentioned,

Look, where in the past 35 years have we produced ten original drugs which we can claim is the results of our R&D activities. We have not, but some pharmaceutical companies such as Pfizer which is American but has shareholders from England, Russia, and Japan did. They work together and have very strong R&D, so they produce some drugs which can be sold around the world. (TM6)

Pharmaceutical pricing is one of the other effective issues in R&D. In Iran, this process is under government's control, therefore, most of the time R&D costs are neglected in drug pricing. In recent years, the Iranian government has tried to solve this issue through establishment of knowledge-based companies. One of the interviewees said,

Look, we have had problems in R&D, and we still have and if we continue like this we will always have problems. A big part of it roots in pharmaceutical pricing. The price of drugs is not suitable, I mean, companies say that we

**Table 2** The Conceptual Framework Extracted From Interviews And Content Analysis (N=35)

Theme	Subtheme	Codes
R&D	<ul style="list-style-type: none"> <li>-Pharmaceutical pricing</li> <li>-GMP conditions</li> <li>-Market role</li> <li>- R&amp;D policy making</li> <li>-Budget allocation</li> <li>-Supporting knowledge-based companies</li> <li>- R&amp;D infrastructure</li> </ul>	<ul style="list-style-type: none"> <li>-Not having proper infrastructure for R&amp;D</li> <li>-There is no competition between national pharmaceutical companies in order to make them become innovative</li> <li>- Aligning research priorities with national pharmaceutical policies</li> <li>-The establishment of NIMAD center at research deputy of Ministry of Health</li> <li>- Assessing the pharmaceutical needs in the society</li> </ul>
Import and Export	<ul style="list-style-type: none"> <li>-Restrictions on imports</li> <li>-Important role of government in balancing import and export</li> <li>-Restrictions on selling pharmaceutical raw materials</li> <li>-High potential for export among national companies</li> <li>-Lack of aggregate data for import policy making</li> <li>-Applying tariff and non-tariff barriers for imports</li> </ul>	<ul style="list-style-type: none"> <li>-Necessity of changing insurance policies in order to discipline the imports</li> <li>-Companies do not have future prospects on pharmaceutical exports</li> <li>-The role of diplomatic strategies for development of national export</li> <li>-Lack of familiarity with international rules and laws for pharmaceutical exports</li> <li>-Having some tax exemptions for importing raw material</li> </ul>
Procurement	<ul style="list-style-type: none"> <li>-The important role of pricing</li> </ul>	<ul style="list-style-type: none"> <li>-Pharmaceutical pricing is done by Ministry of Health, therefore, sometimes a suitable price is not determined for a drug and companies have no financial motivation for production</li> <li>-Most of the attention within drug and food administration is gone for pharmaceutical procurement</li> <li>-A list of pharmaceutical shortages is usually available</li> </ul>
Supply and Distribution	<ul style="list-style-type: none"> <li>-Establishment of pharmaceutical portal system</li> <li>-Having a capillary network in pharmaceutical distribution</li> <li>-The issue of drug trafficking</li> </ul>	<ul style="list-style-type: none"> <li>-Drugs are being controlled from production to consumption using certain codes</li> <li>-Public has access to drugs even at the remotest areas</li> <li>-Restrictions on supplying some special drugs</li> </ul>

**Notes:** Codes: Interviews were codified using letter "P" (Pharmacist), "TM" (Top Manager), "MM" (Middle Manager), and "OM"(Operational Manager) followed by an ordinary number.

**Abbreviations:** GMP, Good Manufacturing Practice; NIMAD, National Institute for Medical Research Development.

cannot do research and produce something with this price. We need more money to do research. With this price we can only afford our routine expenditures. (OM4)

## Theme Two: Import And Export

The amount of pharmaceutical import and export was one of the other extracted themes. Although the Iranian government has recently tried to control the import and improve the export of national production, there are still some challenges in these areas (Table 4).

The participants expressed that not having proper GMP conditions is one of the most important challenges for exporting national production. One of the participants

said, "We don't have good GMP, and we lose the exporting markets to our competitors. We are not good at drug registration which puts us behind our competitors." (P3)

Our national exporting trend has weakened during recent years. Not having strong exporting teams may be one of the main challenges in this area. According to one of the informants,

Our companies do not have an exporting strategy, because they still can easily survive in the national market and do not need to expand their market internationally. Secondly, we do not have the necessary knowledge for export because we lack some exporting specialists. (TM3)



**Table 3** Challenges Of R&D Sector For National Pharmaceutical Companies (N=35)

Challenges	Solutions
Not having a strategic look at R&D sector	-Investment in knowledge-based organizations -Revising the pricing method for pharmaceutical sector
Lack of proper and enough infrastructure for R&D development	-Creating competition between pharmaceutical companies -Not having a monopoly in pharmaceutical sector - Changing the patenting rules -Creating joint venture between pharmaceutical companies -Supporting and empowering the national pharmaceutical companies both financially and legally -Establishment of research institutions
R&D is costly	-Reverse engineering of some drugs of which the patent has expired -Considering R&D and advertisement costs in drug pricing

**Table 4** Challenges Of Pharmaceutical Sector In Terms Of Import And Export (N=35)

Challenges	Solutions
Lack of proper GMP conditions for pharmaceutical export	-Providing facilities for companies and making them match themselves with GMP guidelines -Holding some educational courses on export and quality improvement
Inability of national production to compete with foreign drugs	-Use of diplomatic relations to overcome barriers for export -Proper marketing -Having pharmaceutical specialists at the top level of management of companies -Using the pharmaceutical market of Persian speaking countries
Selling most of the pharmaceutical raw materials	-Development of export market
Increase in the trend of importing high tech and expensive drugs	-Modifying the insurance system to have these drugs covered -Making policies in order to prevent from imports parallel with national production
Increase in the price of finished product due to old production lines	-Planning in order to provide raw materials -Increasing the production up to nominal capacity -Granting some facilities for pharmaceutical companies
Low quality of national production for export	-Development of R&D activities -Producing some imported drugs within the country
-Weakness in marketing -Unfamiliarity with registration rules in other countries -Too much dependence on some traditional markets	-Developing a product marketing strategy -Planning for and supporting the national companies' advertisements in target markets -Mutual negotiation with various countries in order to ease the drug registration process

Choosing appropriate advertising strategies is also one of the other issues for our national export. For instance, Turkish pharmaceutical companies owe most of their success to their systematic advertisement. However, wrong methods of advertisements can also ruin the companies' fame. One of the participants mentioned,

Recently, a few of Iranian companies competed with each other on winning the Afghanistan pharmaceutical market. They offered some discounts on their products in such a way that their drugs price was a lot cheaper than what they were selling in Iran. This created some doubts on quality of Iranian drugs, but the problem was their advertising methods. (P2)

## Theme Three: Procurement

International changes and sanctions affect the economic status of countries. In addition, the pharmaceutical sector is no exception in this regard. Moreover, provision of pharmaceutical raw materials has been the most challenging issue for our pharmaceutical sector in recent years. Table 5 presents the challenges of pharmaceutical procurement along with the suggested solutions to overcome them.

International sanctions have made the financial interactions between companies very difficult; therefore, Iranian companies are faced with some problems in pharmaceutical procurement. One of the participants said, "Sanctions have a tremendous effect on pharmaceutical market. Your money is blocked in international banks and you can't easily buy what you need." (MM3)

According to our participants, our pharmaceutical procurement sector faces fewer problems and barriers in comparison to other sectors. One of the participants pointed out, "If we solve our financial problems, I think we won't have any serious problem for pharmaceutical procurement. Of course, our companies also need right planning to manage their procurement." (OM2)

## Theme Four: Supply And Distribution

The Iranian government has recently put more focus on supporting the national production. Helping national companies as well as providing facilities for them in order to have a better selling market have become the top priorities of Iranian Ministry of Health. Reaching this goal needs companies to produce high quality drugs. Furthermore, having a strong distribution system is also an important tool to achieve such goal. Iranian pharmaceutical distribution system is challenging with various issues (Table 6).

According to the participants, the excessive number of corporate units at retail level with no license to work, lack of tools and new methods for goods' distribution, and lack of willingness of private and foreign sectors to invest in modern distribution networks are the most important challenges for national distribution system. According to one of the participants,

Right now, one of the issues in distribution is the presence of many companies which most of them lack the basic facilities and do not have the necessary requirements to compete with each other. Therefore, they may try to circumvent the rules and sell drugs illegally to counties such as Iraq or Afghanistan. (TM10)

One of the strengths of our distribution system is the presence of a capillary distribution network. One of the informants said,

Our distribution network is one of the most successful networks around the world. Although, it is not as fast as what we have in Europe, it is really strong and can provide access to drugs even at the remotest areas of the country. (MM1)

## Discussion

The present study aimed to analyze, for the first time, the Iranian pharmaceutical sector policies in order to identify the challenges within different sections of this sector so that proper strategic solutions could be suggested to overcome these challenges. As pointed out by the participants in our study, R&D is one of the most important areas in which international pharmaceutical companies put most of their investment. Most of the companies around the world spend almost more than 4% of their income on R&D.<sup>5</sup>

**Table 5** Challenges Of Pharmaceutical Procurement In Iran (N=35)

Challenges	Solutions
Improper pricing	-Changing the pricing model from cost plus to Reference pricing -Revising the price of nationally produced drugs
Instability in companies' management and policy making	Appointing and retaining good managers in pharmaceutical sector
Small production scale of pharmaceutical companies	-Increasing the production volume through producing some high consumption generic drugs and exporting them to Asian and African counties -Producing high quality drugs which can compete at international levels -Creating joint venture -Companies should move toward producing generic drugs which are legally permitted, so that they can increase their selling.

**Table 6** Challenges Of Iran's Pharmaceutical Distribution System (N=35)

Challenges	Solutions
Drug trafficking	<ul style="list-style-type: none"> <li>-Establishment of a drug information portal to monitor drugs from production to consumption</li> <li>-Increasing the quality of nationally produced drugs in order to compete with foreign drugs</li> <li>-Familiarity of importing companies with internal pharmaceutical needs</li> </ul>
The distribution network is not based on a clear program and therefore it is very difficult to be controlled	<ul style="list-style-type: none"> <li>-Redesigning the operational systems and processes</li> <li>-Training and empowering human resources about modern technologies</li> </ul>
Producing single goods in many factories and not having strong quality brands	<ul style="list-style-type: none"> <li>-Creating competition in sales</li> </ul>

However, this sector is not the first priority for Iranian pharmaceutical companies.<sup>1</sup> The participants expressed that a reason for this lies in the relative stability of Iranian pharmaceutical firms as well as the low competition between these firms. Since we do not have strong competition between Iranian companies to win the market shares and each of them has its own certain market share, they feel no need to invest in their R&D department. On the other hand, the participants in our study stated that R&D requires a long-term investment, but managerial and financial instability of companies along with not having suitable legislation to make companies invest in R&D are the main barriers to achieving this goal. In a study by Ghaffari et al, they also mentioned that not having a strong R&D department is the main obstacle for national pharmaceutical development.<sup>20</sup> Analysis of the interviews suggested that creating joint venture among national pharmaceutical companies can be a proper strategy in order to reduce R&D costs so that companies would be financially strong enough to improve their R&D activities. This is one of the widespread methods used by some countries around the world.<sup>21,22</sup> However, there are both advantages and disadvantages pointed out for this strategy. Its advantages include having economies to scale, and cost sharing. Nonetheless, creating market monopoly in the pharmaceutical sector, removing some small companies from the market, increased drug prices, and less governmental control of pharmaceutical pricing are among the disadvantages.<sup>5</sup> Results of a study carried out by Guennif et al also supported findings of our study.<sup>23</sup>

One of the concerns of the participants was that private companies cannot properly invest in R&D activities due to the high costs of raw materials' production, low marginal

profit for pharmaceutical products, and weak governmental supporting policies; so, they are a lot far from innovation and creativity within pharmaceutical sector. In addition, they pointed out that Iranian universities support research and projects that can result in published articles, but such support should be provided for those studies which can bring about a new and innovative product. Creating a comprehensive recording network for all tests and research can prevent doing repetitive projects and will save the research budget as well. This has also been noted in some other national studies.<sup>24,25</sup>

Participants in this study indicated that governments' supporting policies play a paramount role in development and growth of national pharmaceutical companies. This has also been pointed out in different studies,<sup>26-28</sup> so we cannot ignore the role of government as the steward and legislator for the pharmaceutical sector. However, results of our study showed that government intervention has created some inefficiencies for some parts of the pharmaceutical sector. In our perspective, this may be because Iranian pharmaceutical companies are neither completely private nor fully governmental but something between these two. Some Iranian companies are seemingly private, but in fact they are supported by the government. In other words, here the government is the main competitor of the private sector, and this has created a kind of governmental monopoly. According to Ding et al, governments should play their monitoring and policy making roles and provide suitable facilities for companies so that they improve their GMP conditions and can compete with their competitors.<sup>29</sup>

The Iranian pharmaceutical sector has always lacked a proper strategy for exporting their pharmaceutical products.<sup>5</sup> As expressed by the participants, unfamiliarity with



international markets is the main reason for this weakness. Some other studies have also observed this issue.<sup>30,31</sup> Joining World Trade Organization (WTO) will be a suitable solution for overcoming this barrier. According to Rahimi et al, this will help companies improve their technical knowledge, meet international guidelines and standards, enhance their competing abilities, and, finally, find better exporting markets for their products.<sup>32</sup> On the other hand, joining WTO will also help Iranian companies increase their imports through collaboration with foreign companies.

One of the key strengths of our study is the use of a qualitative approach, allowing participants to explain their own experiences and opinions individually. This methodology has allowed the description of the main issues in our setting. As we benefited from a diversity of age, gender and professional experience of the study participants in our study, we are confident in our findings.

Probably, one limitation of our study could be the unavailability of some major potential participants whom we could not interview due to some political and security issues.

## Conclusion

Despite having better potential to become one of the leading sectors in the region, the Iranian pharmaceutical sector has failed to achieve this goal for the past years. According to the results of the present study, having a super-concentrated planning system for both national and imported pharmaceutical products within the government, applying ineffective and inflexible pricing system which reduces companies' motivation to be innovative, and presence of some very strong semi-public companies are the most challenging issues for this sector. On the other hand, not including R&D expenditures in pharmaceutical pricing, and not paying attention to intellectual property rights have motivated national companies to only think about making their products domestic or produce the generic forms of available foreign drugs. However, national production is also heavily dependent on importing raw materials. The result of such dependency showed itself during the recent sanctions through a dramatic increase in pharmaceutical shortages as well as imposing a huge amount of costs on the public.

The results of the current study suggest that establishment of rules related to intellectual property rights can gradually encourage foreign investors to come to Iran, and this will provide a great opportunity for technology and knowledge transfer for the Iranian pharmaceutical sector. Clearly, such policy along with investment in exporting national products as well as creation of

knowledge-based institutions will improve the status of the Iranian pharmaceutical sector worldwide.

## Abbreviations

WTO, world trade organization; R&D, research and development; GMP, good manufacturing practice.

## Ethics Statement

All information was anonymously obtained from participants, and they were fully assured that their personal information would remain confidential and data would be used for research purposes only. Informed verbal consent was obtained from all participants. The study was reviewed and approved by ethics research committee of Tehran University of Medical Sciences, Iran, Iran.

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## Author Contributions

All authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no conflicts of interest in this work.

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